DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 19, 2015

Stryker Corporation
Ms. Soraya King
Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

Re: K143546
Trade/Device Name: Imbibe Aspirating XIA Taps™
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW, LXH
Dated: December 22, 2014
Received: December 23, 2014

Dear Ms. King:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143546

Device Name
Imbibe Aspirating XIA TapsTM

Indications for Use *(Describe)*
The Imbibe Aspirating XIA TapsTM are for use in aspirating bone marrow or autologous blood by use of a syringe. The bone marrow or autologous blood may be combined with bone graft or bone void filler.

The Imbibe Aspirating XIA TapsTM are also for use as bone screw starters and bone taps.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Attachment 4 – FDA Additional Information Request – Revised Section 009

Section 009	**510(k) Summary: Imbibe Aspirating XIA Taps™**
Submitter:	Stryker Spine 2 Pearl Court Allendale, New Jersey 07401
Contact Person	Soraya King Regulatory Affairs Specialist Phone: 201-760-8296 Fax: 201-962-4296 Email: Soraya.King@Stryker.com
Date Prepared	March 3, 2015
Trade Name	Imbibe Aspirating XIA Taps™
Device Common Name	Aspirating Biopsy Bone Taps
Proposed Class	Class II
Classification Name and Number	Gastroenterology-urology biopsy instrument, 21 CFR 876.1075 Orthopedic manual surgical instrument, 21 CFR 888.4540
Product Code	KNW LXH
Predicate Devices	The Imbibe Aspirating XIA Taps™- was shown to be substantially equivalent to the devices listed below: • Stryker Orthobiologics Imbibe Bone Marrow Aspirate Needle (K050795)
Device Description	The Imbibe Aspirating XIA Taps™ are manually operated surgical instruments used to assist with aspiration of bone marrow (BMA) and autologous blood by use of a syringe. The taps will be provided in 4.5mm, 5.0mm, 5.5mm, 6.0mm, 6.5mm, and 7.5mm diameters. The instruments are cannulated with fenestrated distal ends which serve as ports of entry for the BMA and autologous blood. The proximal end of the taps contain an over molded Luer-Lock fitting for syringe connection and BMA/autologous blood extraction. The tips are also threaded to assist in bone preparation and bone screw starter. The main body of the Imbibe Aspirating XIA Taps™ is manufactured from medical grade stainless steel and the Luer-Lock fitting from acrylonitrile butadiene styrene (ABS). The subject device is not intended to be used as a delivery unit. All materials used have acceptable biocompatibility results as per ISO 10993. The devices will be provided as single-use,

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Attachment 4 – FDA Additional Information Request – Revised Section 009

Section 009	**510(k) Summary: Imbibe Aspirating XIA Taps™**
	sterile packed instruments.
Intended Use and Indications for Use	The Imbibe Aspirating XIA Taps™ are for use in aspirating bone marrow or autologous blood by use of a syringe. The bone marrow or autologous blood may be combined with bone graft or bone void filler. The Imbibe Aspirating XIA Taps™ are also for use as bone screw starters and bone taps.
Summary of the Technological Characteristics	The Imbibe Aspirating XIA Taps™ are substantially equivalent to the predicate device in terms of function, principals of operation, technological characteristics, materials of construction. The subject Imbibe Aspirating XIA Taps and the predicate Imbibe Needle share similar design features: • Main body/shaft is cannulated • Fenestrated distal end (tip) • Affixed with an ABS Luer-Lock fitting for syringe attachment

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COMPARISON OF THE IMBIBE ASPIRATING XIA TAPS™ AND THE PREDICATE DEVICE		
Attribute	**Subject Device** **Imbibe Aspirating XIA Taps™**	**Predicate Device** **Imbibe Bone Marrow Aspiration Needle** **510(k) #K050795**
Indications for Use	The Imbibe Aspirating XIA Taps™ are for use in aspirating bone marrow or autologous blood by use of a syringe. The bone marrow or autologous blood may be combined with bone graft or bone void filler. The Imbibe Aspirating XIA Taps™ are also for use as bone screw starters and bone taps.	The Imbibe Bone Marrow Aspiration Needle is for use in aspirating Bone Marrow or Autologous blood by use of a syringe. The bone marrow or autologous blood may be combined with bone graft or bone void filler.
Intended Use	Intended to be used as a bone marrow and autologous blood aspirating needle/instrument. Device can also be used to prepare the bone, and initiate a pathway for bone screw insertion.	Intended to be used as a bone marrow and autologous blood aspirating needle/instrument. Device can also be used to prepare the bone, and initiate a pathway for bone screw insertion.
Product Code	KNW – Gastroenterology-urology biopsy instrument, 21 CFR 876.1075 LXH - Orthopedic manual surgical instrument, 21 CFR 888.4540	KNW – Gastroenterology-urology biopsy instrument, 21 CFR 876.1075
Fenestrated Holes	Distal working-tips contain fenestrations as port of entries for the BMA and autologous blood.	Distal working-tips contain fenestrations as port of entries for the BMA and autologous blood.
Device is Cannulated	Cannulation begins at the fenestrated holes and ends at the Luer Lock fitting attachment point located just below the quick connect handle.	Cannulation begins distal end (tip) and ends at the Luer Lock fitting attachment point located at the top of the device.
Depth Markings on Needle	The laser etching indicates the depth of penetration and helps to determine proper bone screw length.	The laser etching indicates the depth of penetration.
Luer Fitting	Equipped with a male Luer Lock connection for syringe attachment to be used BMA and autologous blood extractions.	Equipped with a male Luer Lock connection for syringe attachment to be used BMA and autologous blood extractions.
Syringe	Any commercially available surgical grade syringe equipped with a female Luer Lock fitting. Syringe not provided with device.	Any commercially available surgical grade syringe equipped with a female Luer Lock fitting. Syringe not provided with device.

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Traditional 510(k) STRYKER SPINE Imbibe Aspirating XIA Taps™

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COMPARISON OF THE IMBIBE ASPIRATING XIA TAPS™ AND THE PREDICATE DEVICE		
Attribute	**Subject Device** **Imbibe Aspirating XIA Taps™**	**Predicate Device** **Imbibe Bone Marrow Aspiration Needle** **510(k) #K050795**
Working-Tip Design	Threaded Needle Tip	Smooth Pointed Needle Tip (Trocar Tip Stylet) or Smooth Blunt Needle Tip (Bullet Tip Stylet)
Handle Design	Compatible with several Stryker handles with a slot groove connection point. Varied handle styles to accommodate surgeon's preference. Handle is not included with the device.	Asymmetric handle-contour fit the physician's hand. Handle is part of the design of the device.
Sizes	Available in diameters of 4.5mm, 5.0mm, 5.5mm, 6.0mm, 6.5mm, and 7.5mm	Various sizes
Principle of Operation	• Once access to the desired anatomical surgical site is obtained, the subject device can be used to pierce through the cortical bone layer, prepare the bone, initiate a bone screw pathway, and aspirate BMA/autologous blood. • A surgical grade syringe is attached to the mating Luer Lock Fitting to collect the bone marrow and blood aspirate. • Aspiration is achieved when the syringe plunger is pulled back. • The collected BMA/autologous blood can be mixed with bone void filler or bone graft material such as allograft, autograft, or synthetic bone graft.	• Once access to the desired anatomical surgical site is obtained, the subject device can be used to pierce through the cortical bone layer, prepare the bone, initiate a bone screw pathway, and aspirate BMA/autologous blood. • A surgical grade syringe is attached to the mating Luer Lock Fitting to collect the bone marrow and blood aspirate. • Aspiration is achieved when the syringe plunger is pulled back. • The collected BMA/autologous blood can be mixed with bone void filler or bone graft material such as allograft, autograft, or synthetic bone graft.
Biocompatible	Stainless Steel, ABS	Stainless Steel, ABS

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COMPARISON OF THE IMBIBE ASPIRATING XIA TAPS™ AND THE PREDICATE DEVICE		
Attribute	**Subject Device** **Imbibe Aspirating XIA Taps™**	**Predicate Device** **Imbibe Bone Marrow Aspiration Needle** **510(k) #K050795**
Materials		
How Supplied	Sterile packed, single-use device	Sterile packed, single-use device
Sterilization Method	Gamma irradiation, 10^{-6}	Gamma irradiation, 10^{-6}

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Summary of Non-Clinical Testing	Performance testing was conducted for the Imbibe Aspirating XIA Taps™ and demonstrated substantially equivalent performance to the identified predicate device system. The following tests were performed: • Luer Lock Fitting (per ISO 594-2) • Air Leakage (per ISO 594-2) • Separation Force of the Luer Lock Fitting (per ISO 594-2) • Unscrewing Torque (ISO 594-2) • Resistance to Overriding (per ISO 594-2) • Pre-clinical testing was conducted using an animal model to demonstrate substantial equivalency performance of the bone marrow and autologous blood aspiration functionality. Laboratory tests were conducted in compliance with applicable Good Laboratory Practices (GLP) requirements stipulated in 21 CFR Part 58.
Conclusion	Based upon a comparison of intended use, technological characteristics, and device performance in the non-clinical testing listed above, the Imbibe Aspirating XIA Taps™ has demonstrated substantial equivalence to the identified predicate device system.